

CERTIFICATE OF ANALYSIS



Recombinant Human albumin

Storage: -20°C

Name of Product: RECOMBINANT HUMAN ALBUMIN (Lyophilized powder in 1X PBS)		Revision No.:	00
Batch No.	FBB300124	Date of Release	19-01-2024
Mfg. Date	01-2024	STP Number	STP002-00
Retest Date	07-2024	Page No.	1 of 1

S. No.	Test	Specification	Results
1	Description	A Off white to pale yellow powder	Complies
2	Identification: Peptide Mapping	The peptide map chromatographic profiles of the sample solution are similar to those of the standard solution	Complies
3	pH	6.4 to 7.4	7.0
4	Loss on drying	Not more than 10%	4.5%
5	Protein content	> 90.0%	95.5%
6	Assay: a) Albumin content Purity by HPLC-GPC	≥ 99.0%	99.21%
	b) Impurities: High Molecular weight proteins by HPLC method	≤ 1.0 %	0.2%
	c) Purity by Native PAGE	≥ 99.0% (w/w)	> 99.95%
7	Host Cell Proteins	≤ 100 ppm/g of protein	Complies
8	Host Cell DNA	≤ 10 ppm/g of protein	Complies
9	Bacterial Endotoxin	< 1 USP Endotoxin Unit/ mg of Recombinant Albumin Human	Complies

REMARKS: The Product [✓]Complies / ~~Does Not Comply~~ as per specification No. SPEC002-00.

	Prepared by	Reviewed by	Approved by
Name	Deepali	Mansi	P. Sri Lakshmi
Department	Quality Control	Quality Assurance	Quality Assurance
Designation	Officer	Assistant Manager	Deputy Manager
Sign & Date	 19-01-2024	KM 19-01-2024	 19-01-2024